



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

40

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/260,037	03/02/99	YACOBY-ZEEVI	910/13

HM12/1006

DR MARK FRIEDMAN LTD
C/O ANTHONY CASTORINA
2001 JEFFERSON DAVIS HIGHWAY
SUITE 207
ARLINGTON VA 22202

EXAMINER
HUTSON, R

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 10/06/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/260,037

Applicant(s)
Yacoby-Zeevi

Examiner
Richard Hutson

Group Art Unit
1652



☒ Responsive to communication(s) filed on Mar 2, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-53 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-53 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1652

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 1-8 drawn to biological preparation comprising an extracellular matrix degrading enzyme, classified in class 435, subclass 183.
- II. Claim 9-12 and 14, drawn to genetically modified cells, classified in class 435, subclass 325.
- III. Claim 15-21, drawn to a method of repairing tissue, classified in class 424, subclass 93.21.
- IV. Claim 22-25, drawn to a method of implanting tissue, classified in class 424, subclass 94.1.
- V. Claim 26-31, drawn to a method of cell transplantation, classified in class 424, subclass 93.21.
- VI. Claim 32-39, drawn to a method of gene therapy, classified in class 514, subclass 44.
- VII. Claim 40-46, drawn to a method of delivering a biological material across a biological blood barrier, classified in class 424, subclass 94.1.
- VIII. Claim 47-51, drawn to a method of delivering a cell across a biological blood barrier, classified in class 424, subclass 93.21.

Art Unit: 1652

- IX. Claim 52-53, drawn to a method of managing a patient having an accumulation of mucoid, mucopurulent or purulent material containing glycosaminoglycans, classified in class 424, subclass 94.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the biological preparation of Group I, and the genetically modified cells of Group II each comprise a chemically unrelated structure capable of separate manufacture, use and effect. The peptide of Group I is comprised of amino acid sequence and the cells Group II are living material.

Inventions I and IV, VII or IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the biological preparation product, comprising an extracellular matrix degrading enzyme of group I can be used in each of the claimed separate methods, or in methods to synthesize antibodies against the extracellular matrix degrading enzyme.

The cells of group II are unrelated to the methods of groups IV, VII or IX, as they are neither used nor made by the methods of groups IV, VII or IX.

Art Unit: 1652

Inventions II and III, V, VI, or VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the cells of group II can be used in each of the claimed separate methods, III, V, VI, or VIII, or in methods to synthesize the extracellular matrix degrading enzyme.

The biological preparation of group I is unrelated to the methods of groups III, V, VI, or VIII, as they are neither used nor made by the methods of groups III, V, VI, or VIII.

The methods of groups III-IX are independent as they comprise different steps, utilize different products and produce different results.

1. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. *"For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP 808.02."* (see MPEP 803). The serious burden of search has been established by the different fields of search of the inventions and the fact that the fields of search are not coextensive.

Art Unit: 1652


A telephone call was made to Mark Friedman on 9/30/99 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on M-F from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapy Achutamurthy (Murthy), can be reached on (703) 308-3804. The fax number for Official Papers to Technology Center 1600 is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP 1600
1600

Richard Hutson, Ph.D.